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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,005	10/24/2003	John W. Forsberg	1023-294US01	9349
28863	7590	06/01/2006	EXAMINER	
SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			FLORY, CHRISTOPHER A	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,005

Applicant(s)

FORSBERG ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-31 is/are pending in the application.
- 4a) Of the above claim(s) 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/2/04, 10/12/04...

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 9/8/05; 10/7/05 and 12/14/05

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 19 April 2006 is acknowledged. The traversal is on the ground(s) that Applicant believes that the process of Group II cannot be practiced by another apparatus because independent claim 22 recites the method in a medical device programmer. This is not found persuasive because PDAs and cell phones are well known in the art to be used as medical device programmers or in conjunction with medical device programmers to telemeter with an implantable device and with other programmers (e.g. a patient programmer communicating with the clinician's programmer). Yet, PDAs and cell phones are capable of other uses both within and outside of the medical application that represent clearly divergent technology that still employs a method of using an infrared interface to update operating system or other programs. Furthermore, the claimed infrared communication session is effective between the medical device programmer (or cell phone, or PDA) and the device that programs the programmer (e.g. a personal computer or another cell phone), not between the programmer and the implanted medical device, giving further justification to Examiner's original argument.

Applicant also argues that Group I cannot practice another process due to a recitation of the device being a medical device programmer with an infrared interface. This is not found persuasive because the recitation of a medical device programmer is located in the preamble of the claim. It has been held in the court that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion

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of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). Furthermore, functional language attached to the structural limitations of a claim is considered to be anticipated when an art-recognized equivalent to the structure is disclosed that yields the same expected results. Therefore, communication with a programming device could be achieved using an art-recognized equivalent to IR, such as RF or Bluetooth.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 19 April 2006.

Drawings

1. The drawings are objected to because Figure 16 improperly labels antenna circuit board 106 with the reference tag 104 (which is assigned to the display circuit board).
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 76 (Fig. 6A).
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

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description: connector 107 (paragraphs [102]-[104] and [110]); button moldings 100, 102 (paragraph [110]); connector 113 (paragraph [115]).

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: there are several typographical errors related to the reference characters in the Detailed Description. In paragraph [59], "patient 12" should be replaced with --patient 18-- and "IMD 14" should be replaced with --IMD 12--. In paragraph [66], "Processor 22 also controls a telemetry interface to transmit" should include the reference character and so read --Processor 22 also controls a telemetry interface 30 to transmit--. In paragraph [72], "internal antenna 22" should be changed to --internal antenna 32--. In paragraph [74], "input 26" should be changed to the more specific reference --push button 26--. In

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paragraphs [110] and [114], "programmer 22" should be corrected to read --programmer 20--. In paragraph [111], "top housing cover 98" should be changed to --top housing cover 96--. Paragraph [115] contains reference to both "jack 114" and "plug 114," one of which should be changed to coincide with the other for clarity. In paragraph [135], "Antenna circuit board 110" should be corrected to read --Antenna circuit board 104--. In paragraph [139], "antenna circuit board 1104" should be corrected to read --antenna circuit board 104--.

Appropriate correction is required.

Claim Objections

6. Claim 14 is objected to because of the following informalities: Examiner objects to the definiteness of the limitation "opposite the second circuit board." Applicant should consider amending the claim with language that imparts definite function, such as --positioned on the first circuit board to avoid noise and electromagnetic interference from the second board--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1- 7, 10, 17, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III et al. (US Patent Publication 2002/0002326).

Regarding claims 1, 5, and 21, Causey, III et al. discloses a medical device programmer (ABSTRACT; Fig. 1) for an implantable neurostimulator (paragraph [118]) comprising an infrared interface to receive changes to software executed by a processor within the programmer (paragraphs [68], [80], [86], and [98]); and an infrared interface controller (Fig. 21, transmitter/receiver 1017).

Regarding the clause that the infrared communication session is initiated for a finite amount of time, Causey, III et al. discloses that the data I/O port uses IR technology to upload new program instructions from a computer (paragraph [98]). By the fact that a computer program is of a finite size, the transfer of such a program is inherently finite in length, and therefore an IR communication session transmitting the data is also finite. Furthermore, even if the IR port were constantly in communication when the device is turned on, the powering down of the unit would also constitute a finite end to the IR communication session. Therefore, this limitation does not distinguish the instant application over the prior art.

Regarding the clause that the infrared communication session is initiated in response to power-up of the programmer, this is inherent because the IR link has to be initiated and active for any data to be transceived between the patient programmer and it's programming device. Therefore, because communication initiation in response to

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power-up is understood to be an inherent property of the Causey, III et al. system, the instant application is not distinguished over the prior art in this regard.

Regarding claims 3 and 4, Causey, III et al. discloses that the software changes comprise changes to an operating system or changes to medical device programs (paragraph [98]).

Regarding claim 6, Causey, III et al. shows a software loading port (Fig. 3, port 120).

Regarding claim 7, a JTAG interface is a well-known and inherent component of any electronic system using EEPROM or flash memory (paragraphs [62], [97]).

Therefore, this claim limitation does not structurally distinguish the instant application over the prior art of Causey, III et al.

Regarding claim 10, it is an inherent property of any functional electronic device using an operating system to contain software that includes instructions to implement that operating system. Therefore, this claim limitation does not distinguish over the prior art.

Regarding claim 17, Causey, III et al. discloses an LCD display (paragraph [62]).

Regarding claims 2 and 20, the active time requirements of 5 to 10 seconds and less than or approximately equal to 10 seconds, respectively, are not limiting over the Causey, III et al. device because Causey, III et al. does not explicitly teach a system that shuts off its IR interface with a different time requirement. If the Causey, III et al. system remains in use for an hour or is always on, then the IR interface is active for 5-10 seconds by nature of being on for longer than that. Likewise, if the patient or

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clinician using the device powers down after 8 seconds, then the IR interface has been active for 8 seconds, which satisfies the language of claims 2 and 20. Therefore, claims 2 and 20 do not patentably distinguish the instant application from the prior art.

9. Claims 1-10, 17, and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Meadows et al. (US Patent 6,516,227).

Regarding claims 1, 5, 19 and 21, Meadows et al. discloses a medical device programmer for an implantable neurostimulator (TITLE; ABSTRACT; column 5, lines 25-35) comprising an IrDA infrared interface (Fig. 7D-2, IrDA module 640) to receive changes to software executed by a processor within the programmer (Fig. 7D, microprocessor 620) during an infrared communication session (column 39, lines 14-42); and a controller (UART circuit 644 and microprocessor 620) to control the infrared interface.

Regarding the clause that the infrared communication session is initiated for a finite amount of time, Meadows et al. discloses that a telecommunicative link is established each time the patient or medical personnel change a stimulus parameter or initiate a charging session (column 17, lines 61-65), which means that each communication must necessarily terminate at some time before the next begins. Likewise, Meadows et al. discloses that the patient handheld programmer (HHP) is automatically turned off after a period of disuse, e.g. 1 minute (column 36, lines 50-53). Even if the unit were in constant IR communication with the external linking device, this automatic turning off of the HHP unit would also constitute the terminus of a finite

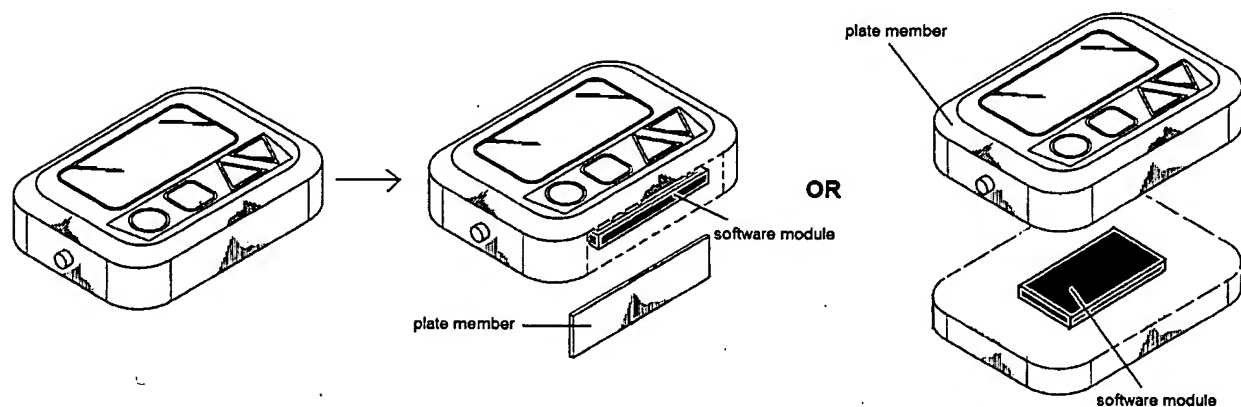
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infrared session. Therefore, this claim limitation does not distinguish the instant application over the prior art.

Regarding the clause that the infrared communication session is initiated in response to power-up of the programmer, Meadows et al. discloses the following: that the clinician programmer is in telecommunicative contact with the HHP in a likewise fashion that the HHP is in communication with the implantable pulse generator (IPG) (column 17, lines 3-6); that the HHP communicates with the IPG in order to control the operating program and stimulation parameters, taken to be a "medical device program" (column 16, line 60 through column 17, line 13); that the IPG telemeters data to the HHP each time a communication link is established (column 17, lines 55-60) and on power-up (Fig. 4D; column 37, lines 7-11)); and further, that all programming systems used by the HHP and clinician's programmer are always appropriately synchronized so that any changes from one are reflected in the other (column 36, lines 24-28). Thus it is understood that the clinician programmer controls the operating program and stimulation parameters (i.e. "the medical device program") of the HHP in a likewise fashion that the HPP controls the operating functions of the IPG. From this disclosure, one skilled in the art would further recognize that it is an inherent function of the Meadows et al. device that the infrared communication session is initiated on power-up of the HHP in order for the HPP and clinician programmer to be "always appropriately synchronized." Therefore, because communication initiation in response to power-up is understood to be an inherent property of the Meadows et al. apparatus, the instant application is not distinguished over the prior art in this regard.

Regarding claims 3 and 4, Meadows et al. discloses that the software changes comprise changes to an operating system or changes to medical device programs (column 16, line 60 through column 17, line 13; column 36, lines 24-28).

Regarding claims 6 and 8, the device of Meadows et al. is shown in Fig. 5 to be constructed of a housing with more than one part (Fig. 5, column 36, line 46 discloses an upper housing). Any electronic device comprising housing of more than one part and containing software loaded on a memory inherently comprises a software loading port, where the port is considered to be the open portion of the housing in which the software-loaded circuitry is being inserted or affixed, and the other portion of the housing is considered to be the plate member covering the loading port.



Regarding claim 9, Meadows et al. discloses that the plate member be printed with identifying information (column 38, line 55 through column 39, line 15). Given the configuration shown on the right side of the figure above, the disclosed labels on the buttons clearly satisfy this claim limitation.

Regarding claim 7, a JTAG interface is a well-known and inherent component of any electronic system using SRAM or EEPROM (Fig. 7D-2). Therefore, this claim

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limitation does not structurally distinguish the instant application over the prior art of Meadows et al.

Regarding claim 10, it is an inherent property of any functional electronic device using an operating system to contain software that includes instructions to implement that operating system. Therefore, this claim limitation does not distinguish over the prior art.

Regarding claim 17, Meadows et al. discloses an LCD display (Fig. 7D-1, LCD module 240; column 39, lines 15-42).

Regarding claims 2 and 20, the active time requirements of 5 to 10 seconds and less than or approximately equal to 10 seconds, respectively, are not limiting over the Meadows et al. device because Meadows et al. does not explicitly teach a system that shuts off its IR interface with a different time requirement. If the Meadows et al. system remains in use for an hour or is always on, then the IR interface is active for 5-10 seconds by nature of being on for longer than that. Likewise, if the patient or clinician using the device powers down after 8 seconds, then the IR interface has been active for 8 seconds, which satisfies the language of claims 2 and 20. Therefore, claims 2 and 20 do not patentably distinguish the instant application from the prior art.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 11, 12, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al.

Regarding claims 11, 12, and 14, Meadows et al. discloses the invention substantially as claimed including a first and second circuit board (Fig. 7A, button pad 241 is disclosed as being on a separate printed circuit board; column 36, lines 44-49), but does not disclose expressly that the telemetry circuitry and antenna be on the first board and the display, display circuitry and control circuitry be on the second board. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with the two circuit boards as an obvious expedient to simplifying the manufacturing process and for the purpose of making the device of a size similar to other hand held devices that use a hinged two board design, such as cellular phones.

Therefore, it would have been obvious to modify the system/method of Meadows et al. to obtain the invention as specified in the claims, and the instant application does not patentably distinguish over the prior art.

Regarding claim 15, Meadows et al. discloses the invention substantially as claimed including that the device is small enough to hold comfortably in one hand powered by e.g. a single AA-sized battery in an internal battery compartment (column 38, line 55 through column 39, line 22), but does not expressly disclose that the battery bay extends at least partially into the internal antenna aperture. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the

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invention to modify the system as taught by Meadows et al. by extending the battery bay into the antenna aperture, because Applicant has not disclosed that such a positioning provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a battery compartment away from the antenna source or even an external power source since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Meadows et al.

Furthermore, having a battery bay that extends into an aperture defined by the antenna is almost inherent in the nature of a device small enough to be held in the hand (the figure provided above with a battery in place of the memory module provides a good example of this). Still further, the aperture as claimed could be defined as the housing of HHP 202, of which the battery bay is an inherently integral and internal part.

Therefore, it would have been an obvious matter of design choice to modify the system/method of Meadows et al. to obtain the invention as specified in claim 15, which fails to distinguish the instant application over the prior art.

Regarding claim 18, Meadows et al. discloses the invention substantially as claimed but does not disclose expressly that the infrared interface is positioned on a lower side surface of the housing. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. by positioning the infrared interface on a lower side surface of the housing, because Applicant has not disclosed that such a positioning provides an

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advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an alternate placement of the IR interface since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Meadows et al. Therefore, it would have been an obvious matter of design choice to modify the system/method of Meadows et al. to obtain the invention as specified in the claim.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al. in view of Stanton et al. (US Patent 6,249,703).

Meadows et al. discloses the Applicant's invention substantially as claimed except for an external antenna. Stanton et al. teaches the use of an external antenna (Fig. 1, external antenna 28) with a patient programmer (10) to eliminate the need to place the programmer over the implant site during programming sessions, which is helpful for patients who cannot easily reach the implant site due either to physical condition or location of the implant site (column 6, lines 6-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with an external antenna for the same advantages taught by the Stanton et al. patent (motivation to combine provided by Stanton et al., column 6, lines 6-17).

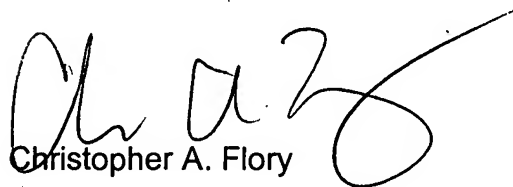
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

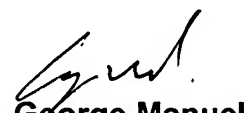
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher A. Flory

24 May 2006



George Manuel
Primary Examiner